ENVIRONMENTAL PROTECTION AGENCY

[OPPTS-47002K; FRL-4059-9]

RIN 2070-AC31

TSCA Section 4(a)(1)(B) Final Statement of Policy; Criteria for Evaluating Substantial Production, Substantial Release, and Substantial or Significant Human Exposure

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final Statement of Policy.

SUMMARY: EPA is articulating standards and criteria for making findings it will use in implementing its authority under the Toxic Substances Control Act (TSCA) section 4(a)(1)(B)(i). Under this policy, EPA will use as guidance threshold amounts to make "substantial" production, release, and human exposure findings under TSCA section 4(a)(1)(B). However, EPA may also make such findings in situations where the quantitative numerical thresholds are not met if additional factors exist. EPA will continue to develop and refine the criteria as its experience with chemical substances and mixtures (chemicals) considered for testing evolves, particularly with regard to the findings of "significant" human exposure, for which EPA is not establishing a minimum numerical threshold in this notice. This notice also addresses specific issues related to EPA's existing cumene test rule (July 27, 1988, 53 FR 28195).

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SUPPLEMENTARY INFORMATION:

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EPA is articulating guidelines for finding that "a chemical substance or mixture is or will be produced in substantial quantities, and (I) it enters or may reasonably be anticipated to enter the environment in substantial quantities, or (II) there is or may be significant or substantial human exposure to such a substance or mixture," under TSCA section 4(a)(1)(B)(i). In *Chemical Manufacturers Association v. Environmental Protection Agency*, 899 F.2d 344 (5th Cir. 1990), the Fifth Circuit Court of Appeals (the "Court") remanded to EPA the rule issued pursuant to 4(a)(1)(B) for cumene testing and required EPA to articulate criteria for the findings EPA made in the cumene test rule (53 FR 28195, July 27, 1988). EPA has decided to use this opportunity to articulate criteria for making all findings under section 4(a)(1)(B)(i) of TSCA.

This notice does not address how EPA will set priorities for testing or how EPA will determine the specific tests to be performed. Rather, this notice addresses one element in EPA's process for selecting appropriate candidates for testing — i.e, how EPA will determine whether the chemical is or will be "produced in substantial quantities," whether it "enters or may reasonably be anticipated to enter the environment in substantial quantities," and whether there is or may be "significant or substantial human exposure," as used in TSCA section 4(a)(1)(B)(i).

I. Introduction

A. Remand

On April 12, 1990, the Fifth Circuit Court of Appeals remanded to EPA the TSCA section 4 test rule for cumene based on a challenge to the rule by the Chemical Manufacturers Association (CMA). *CMA v. EPA*, 899 F.2d 344 (5th Cir. 1990) (hereinafter "cumene decision"). The Court generally upheld EPA's factual findings in the rule as being supported by substantial evidence but instructed the Agency to "articulate the standards or criteria on the basis of which it found the quantities of cumene entering the environment from the facilities in question to be 'substantial'." 899 F.2d at 360. In this notice, EPA is articulating standards and criteria it will use in making findings under section 4(a)(1)(B)(i) of TSCA. Additionally, EPA is responding to the instructions by the Court regarding the application of such criteria to the cumene rule.

B. Background

Congress enacted TSCA to give EPA the authority to assess and prevent unreasonable risks associated with the manufacture, processing, distribution in commerce, use, or disposal of chemicals through a variety of regulatory means. 15 U.S.C. 2601, et seq. This authority includes, among other things, the authority to require chemical testing to develop data for risk assessment, 15 U.S.C. 2603, and the authority to ban chemicals if necessary to prevent unreasonable risks. 15 U.S.C. 2605. A principal tenet underlying TSCA is that "adequate data should be developed with respect to the effect of chemical substances and mixtures on health and the environment and that the development of such data should be the responsibility of those who manufacture and those who process such chemical substances and mixtures." 15 U.S.C. 2601(b)(1). See *Chemical Manufacturers Association v. EPA*, 859 F.2d 977, 980 (D.C. Cir. 1988) (hereinafter "EHA decision"). To accomplish this goal, EPA has established a program for the testing of chemicals.

EPA must make findings under either section 4(a)(1)(A) ("A" finding) or 4(a)(1)(B) ("B" finding) of TSCA before testing may be required of a manufacturer or processor. Both the "A" and "B" findings under TSCA section 4(a)(1) require the Administrator to find that "there are insufficient data and experience upon which the effects of the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or any combination of such activities on health or the environment can reasonably be determined or predicted," and that "testing of such substance or mixture with respect to such effects is necessary to develop such data." 15 U.S.C. 2603(a)(1)(A)(ii)–(iii) and 2603(a)(1)(B)(ii)–(iii).

To require testing under section 4(a)(1)(A) of TSCA the Administrator must find that "the manufacture, distribution in commerce, processing, use, or disposal of a chemical substance or mixture, or that any combination of such activities, may present an unreasonable risk of injury to health or the environment" (emphasis added). In the EHA decision, the Court found this provision to require EPA to establish a "more than theoretical basis" for finding that the chemical may present an unreasonable risk, but that EPA could establish existence and amount of human exposure to the chemical on the basis of inference drawn from circumstances under which the chemical is manufactured and processed. 859 F.2d at 991. This interpretation of the statute "prevents a testing rule based on little more than scientific curiosity, yet allows the Agency to act when an existing possibility of harm raises reasonable and legitimate cause for concern." *Ausimont U.S.A. v. EPA*, 838 F.2d 93, 97 (3rd Cir. 1988).

In contrast to TSCA section 4(a)(1)(A), under TSCA section 4(a)(1)(B), there is no risk-based criterion to satisfy. See 899 F.2d at 347, n.4 (cumene decision). According to the legislative history, the provisions of TSCA section 4(a)(1)(B)(i) reflect the "Conferees' recognition that

there are certain situations in which testing should be conducted even though there is an absence of information indicating that the substance or mixture per se may be hazardous." H. Conf. Rept. 1679, 94th Cong., 2d Sess. (1976), at 61, reprinted in A Legislative History of the Toxic Substances Control Act (Comm. Print 1976) ("Leg. Hist.") at 674; and H. Conf. Rept. 1341, 94th Cong., 2d Sess. (1976), at 18, reprinted in Leg. Hist., at 425. Thus, under section 4(a)(1)(B) of TSCA, EPA can act even in the absence of information that the chemical may be hazardous. Section 4(a)(1)(B)(i) requires the Administrator to find that "a chemical substance or mixture is or will be produced in substantial quantities, and (I) it enters or may reasonably be anticipated to enter the environment in substantial quantities, or (II) there is or may be significant or substantial human exposure to such substance or mixture."

This policy statement sets out EPA's interpretation of section 4(a)(1)(B)(i) of TSCA. This notice is not intended to address EPA's preliminary policy decisions for selecting chemicals as potential candidates for testing. Likewise, it is not intended to address findings made under TSCA sections 4(a)(1)(B)(ii) or (iii), or the scope of testing that may eventually be imposed by EPA. It is only intended to articulate the standards and criteria EPA will use in implementing its authority to make findings under TSCA section 4(a)(1)(B)(i). To this end, EPA published in the **Federal Register** on July 15, 1991 (56 FR 32294), its proposed statement of policy regarding section 4(a)(1)(B)(i) of TSCA. EPA requested comments on its construction of the phrases "produced in substantial quantities," "enters or may reasonably be anticipated to enter the environment in substantial quantities," and "is or may be significant or substantial human exposure" as used in section 4(a)(1)(B)(i) of TSCA.

C. The "B" Policy

Section 4(a)(1)(B)(i) of TSCA requires the Administrator to find that a chemical substance or mixture is or will be produced in substantial quantities, and "(I) it enters or may reasonably be anticipated to enter the environment in substantial quantities, or (II) there is or may be significant or substantial human exposure to such substance or mixture," to impose testing requirements. However, TSCA does not define the criteria or standards to be used, or the meanings of the words "significant" or "substantial." Additionally, the legislative history of TSCA provides no elucidation of these terms. Where a statute is silent or ambiguous on a particular issue, deference is accorded to any reasonable interpretation consistent with the statutory purpose. *Chevron USA, Inc. v. EPA*, 467 U.S. 837, 842–844, (1984); *NRDC v. EPA*, 907 F.2d 1146, 1153 (D.C. Cir. 1990). The Fifth Circuit Court of Appeals recognized this principle when reviewing the cumene test rule. According to the Court, where TSCA and its legislative history provide no definition of a term such as "substantial," "Congress is deemed to have implicitly delegated to the EPA the power to define or interpret 'substantial,' and we will sustain the Agency's interpretation as long as it is rational and consistent with the statutory scheme and legislative history." 899 F.2d at 354.

> [S]ubstantial is an inherently imprecise word. * * * no definition or group of criteria can be established which will function like a mathematical formula, so that for every given set of facts a specific, predictable answer will always be forthcoming. Room must be left for the exercise of judgment.
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> Id. at 359.

Clearly, there is nothing in the statutory language or legislative history that restricts the Agency's allowed interpretation of "substantial" or "significant" to consideration of particular quantities of or other evidence relating to production, release, or exposure. In fact, Congress provided a list of factors which may or may not be considered by EPA in making TSCA section 4(a)(1)(B)(i) findings. H. Rept. 1341, 94th Cong., 2d Sess. (1976), at 18, reprinted in Leg. Hist., at 425. See also cumene decision, 899 F.2d at 356, n.16 ("Moreover, the quoted language in H. Rept. 1341 *** is permissive and expansive in respect to what the EPA may consider and when it may require testing under section 4(a)(1)(B) ***").

In this statement of policy, EPA is exercising its discretion by articulating quantitative thresholds to serve as guidance in making findings of "substantial" production, release, and human exposure. "Significant" human exposure findings will be made on a case-by-case basis. As explained in the proposed policy statement (56 FR 32294), it is EPA's belief that EPA may make findings under section 4(a)(1)(B)(i) of TSCA based on quantitative thresholds. However, EPA does not intend to limit itself to the use of these criteria in making "B" findings and reserves the ability to consider other factors on a case-by-case basis. Such an interpretation is consistent with the legislative history of TSCA and effectuates the policy objectives described in section 2 of TSCA of developing adequate data with respect to chemicals and making the development of that data the responsibility of chemical manufacturers and processors.

II. Response to Public Comments

A. Summary

EPA received written comments on the proposed statement of policy from the Chemical Manufacturers Association (CMA), the Epoxy Resin Systems Task Group of The Society of the Plastics Industry, Inc. (SPI), the Monsanto Company, the Ecological and Toxicological Association of the Dyestuffs Manufacturing Industry (ETAD), the Callery Chemical Company, the Halogenated Solvents Industry Alliance (HSIA), the GAF Chemicals Corporation (GAF), the BASF Corporation (BASF), the Arco Chemical Company (ACC), the U.S. Department of Labor's Occupational Safety and Health Administration (DOL/OSHA), and the U.S. Department of Health and Human Service's National Institute for Occupational Safety and Health (HHS/NIOSH) (Refs. 1–9).

CMA's Acetone and Ketones Panels, Oxo Process Panel, Cumene Panel, Cyclohexane Panel, and Hexamethylene Diisocyanate Panel, and the Diethyl Ether Manufacturers Task Group (Refs. 10–15) also submitted comments which supported, in general, the comments submitted by CMA. These commenters are collectively referred to as "CMA" hereafter in this notice. Comments submitted by these groups which are specific to a proposed test rule for a specific chemical will be addressed, as appropriate, in the final rule for that specific chemical. Those rules will be published in the future. The comment periods were reopened for proposed test rules for Office of Drinking Water Chemicals (55 FR 21393, May 24, 1990), Cyclohexane (52 FR 19096, May 20, 1987), 1,6-Hexamethylene, Diisocyanate (54 FR 21240, May 17, 1989), and *N*-methylpyrrolidone (55 FR 11398, March 28, 1990); See 56 FR 32292 (July 15, 1991). A summary of the comments received on the TSCA section 4(a)(1)(B) proposed statement of policy is included in the following Units II.B. –II.G., along with EPA's responses to comments.

B. Scope of Testing

CMA and other commenters have expressed the concern that, given the criteria articulated in this notice, "nearly 8,000 substances will require [EPA] review under section 4(a)(1)(B)" (Refs. 1 and 5). These comments indicate that many commenters have

misinterpreted the intended and actual scope of this policy. The "B" policy is not intended to be, nor will it be used as an automatic trigger to testing. Nothing in this policy will require EPA to immediately review any of the chemical substances currently in commerce. Rather, this policy statement sets out EPA's interpretation of the findings it must make under section 4(a)(1)(B)(i) and the general factors EPA will consider in evaluating section 4(a)(1)(B)(i)'s applicability in specific cases. This policy statement is not intended to function as a tool for setting testing priorities. Testing priorities will be set by EPA's ongoing efforts in developing a Master Testing List. This list was made available to the public in EPA's Chemicals-in-Progress Bulletin (June, 1990). See also 56 FR 42055 (Aug. 26, 1991) for further information.

Many respondents, including CMA, have indicated their tacit support for the threshold criteria articulated in this policy notice, so long as "B" findings are made only in support of rules requiring only tiered, screening level or "baseline testing" of chemical substances (Ref. 1). CMA opposes utilization of the "B" policy criteria, and indeed, use of EPA's section 4(a)(1)(B) testing authority for any other level of testing.

On the policy as a whole, CMA commented that EPA's proposed criteria under TSCA section 4(a)(1)(B)(i) are reasonable as a basis for requiring screening tests such as the Screening Information Data Set (SIDS) utilized by the Organization for Economic Cooperation and Development (OECD) for high production volume (HPV) chemicals. CMA stated, "EPA's proposed 'B' criteria would provide a suitable basis for selecting substances for such screening tests" (Ref. 1). CMA proposed that, if screening studies reveal the potential for adverse effects, then EPA should add the chemical to a subsequent proposed rule under the authority of TSCA section 4(a)(1)(A), the "may present" finding. CMA proposed that, in the absence of toxicity concerns, EPA should require additional testing only if it concludes that exposure is "unusually great." CMA argued that more rigorous "B" criteria, which take into account all aspects of exposure, must be developed by EPA to select such high exposure substances for additional testing. CMA stated that it would not oppose EPA's criteria if they were incorporated into the tiered approach described above. CMA would oppose EPA's "B" criteria, if they are used for any other purpose. CMA further asserted that if a "B" finding is based "solely on the magnitude of environmental releases, the Agency should limit rules supported by such findings to chemical fate and environmental effects testing" (Ref. 1).

EPA believes that any linkage between the particular numerical threshold criteria articulated in this policy statement, or the particular findings made under TSCA section 4(a)(1)(B)(i), and the nature and scope of testing to be required once such a finding has been made, is misplaced, and indeed, based on a misinterpretation of the scope of EPA's testing authority under section 4 of TSCA.

TSCA section 4(a) states:

(a) TESTING REQUIREMENTS.—If the Administrator finds that—

(1)(A)(i) the manufacture, distribution in commerce, processing, use, or disposal of a chemical substance or mixture, or that any combination of such activities, may present an unreasonable risk of injury to health or the environment,

(ii) there are insufficient data and experience upon which the effects of such manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and

(iii) testing of such substance or mixture with respect to such effects is necessary to develop such data; or

(B)(i) a chemical substance or mixture is or will be produced in substantial quantities, and (I) it enters or may reasonably be anticipated to enter the environment in substantial quantities or (II) there is or may be significant or substantial human exposure to such substance or mixture,

(ii) there are insufficient data and experience upon which the effects of the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and

(iii) testing of such substance or mixture with respect to such effects is necessary to develop such data; and * * *

the Administrator shall by rule require that testing be conducted on such substance or mixture to develop data with respect to the health and environmental effects for which there is an insufficiency of data and experience and which are relevant to a determination that the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture, or that any combination of such activities, does or does not present an unreasonable risk of injury to health or the environment.

15 U.S.C. 2603(a) (emphasis added).

The final paragraph of section 4(a) sets out EPA's authority to require testing once the Agency has made the findings under section 4(a)(1)(A) or (B). The directive of this final paragraph clearly relates to the "data insufficiency" and "testing is necessary" findings of sections 4(a)(1)(A)(ii) and (iii) and (B)(ii) and (iii); it bears no dependence on or other relationship to the findings under either subsection 4(a)(1)(A)(i) or (B)(i).

Thus, once the Administrator has made a finding under TSCA section 4(a)(1)(A)(i) that a substance may present an unreasonable risk, or under TSCA section 4(a)(1)(B)(i) that a substance is or will be produced in substantial quantities and may either enter the environment in substantial quantities or that there may be substantial or significant human exposure to the substance, the Administrator may require any type of testing necessary to address unanswered questions about the effects of the substance. EPA need not limit the scope of testing required to the factual bases for the section 4(a)(1)(A)(i) or (B)(i) findings.

Essentially, under TSCA section 4(a)(1)(B), EPA may require health effects testing even if it has only made a finding that there is or may be substantial entry into the environment of a substance, or require environmental effects testing even if it has only made a finding that there is or may be substantial or significant human exposure to a substance. Clauses (I) and (II) of section 4(a)(1)(B)(i) can be interpreted as mutually exclusive. See cumene decision, 899 F.2d at 357 n. 19. Either finding is sufficient to require testing, so long as EPA finds that data relevant to a determination of whether a substance does or does not present an unreasonable risk of injury to health or the environment are insufficient and that testing is necessary to develop such data. It is the interrelationship of the existing data set and numerous other substance-specific parameters, which are evaluated under subsections (ii) and (iii) of section 4(a)(1)(B), that determines the specific testing requirements, if any, for a particular substance.

EPA notes, however, that while it has the authority to require testing for any health and environmental effects once it has made a finding under either section 4(a)(1)(A)(i) or (B)(i) of TSCA, the Act does not compel EPA to require testing of all health or environmental effects endpoints in all cases. Rather, once EPA has decided that it will require testing, EPA must also determine what data are sufficient and what testing is necessary in each particular case in promulgating specific testing requirements. In addition, once EPA has decided to require testing, EPA also considers, among other factors, "the relative costs of the various test protocols *** and the reasonably foreseeable availability of the facilities and personnel needed to perform the testing required under the

rule." TSCA section 4(b)(1), 15 U.S.C. 2603(b)(1).

Furthermore, if Congress had intended that the testing required under section 4(a)(1)(B) be related to whether the findings are based on information about human exposure or environmental release, it is reasonable to conclude that Congress would have used the word "or" instead of "and" when directing the Administrator to require testing "to develop data with respect to the health and environmental effects *** " in the final paragraph of section 4(a). However, the explicit choice of the word "and" in this final paragraph indicates that Congress authorized EPA to require health and environmental effects testing independent of the basis for an (A)(i) or (B)(i) finding. Indeed, EPA has consistently interpreted the "testing is necessary" under TSCA sections 4(a)(1)(A)(iii) and (B)(iii) to mean that EPA may require any health or environmental effects testing for which data are insufficient and which EPA believes are "capable of developing the necessary information." See 45 FR 48510, 48530 (July 18, 1980).

EPA's broad mandate to require testing is also reflected in the legislative history of TSCA. See H. Rept. 1341, 94th Cong., 2d Sess. (1976), at 3–6, reprinted in Leg. Hist. at 411–414. The breadth of TSCA's authority to require testing is most apparent in TSCA section 4(a)(1)(B) which, according to the Conference Report on TSCA, authorizes EPA to require testing "even though there is an absence of information indicating that the substance or mixture per se may be hazardous." H. Conf. Rept. 1679, 94th Cong., 2d Sess. (1976), at 61, reprinted in Leg. Hist. at 674. See also H. Rept. 1341, 94th Cong., 2d Sess. (1976), at 18, reprinted in Leg. Hist. at 425.

Finally, in the cumene decision, the Court supported EPA's interpretation regarding the relationship between the findings under TSCA subsection 4(a)(1)(B)(i) and subsections 4(a)(1)(B)(ii) and (iii):

A finding under section 4(a)(1)(B)(i) does not alone justify a testing order. It must also be found under section 4(a)(1)(B)(ii) that 'there are insufficient data and experience upon which the effects of the manufacture [or processing, etc.] *** of such substance *** on health or the environment can reasonably be *** predicted.' Similarly, section 4(a)(1)(B)(iii) imposes the further requirement that the testing be 'necessary to develop such data' (emphasis added)— i.e., necessary to render the experience and data sufficient as a basis on which the health and environmental effects of the manufacturing (or processing, etc.) can reasonably be predicted ***. If the EPA properly concludes that the existing data and experience do not suffice as a basis for it to reasonably predict that there will be no health or environmental injury from the manufacturing (or processing, etc.) of the chemical, then affirmative evidence and findings of risk of such injury at hypothetical toxicity levels under section 4(a)(1)(B)(i) are not necessary to provide a nexus between requiring testing under section 4(a)(1)(B) and congressional concern for health and the environment.

899 F.2d at 354–355 (emphasis in original). Given that TSCA section 4(a)(1)(B)(i) gives EPA authority to require health and environmental effects testing even in the absence of information that a substance is hazardous, it is reasonable that the specific testing to be required relates to the data insufficiency and testing is necessary findings under TSCA section 4(a)(1)(B)(ii) and (iii) rather than to the environmental release or human exposure finding made under TSCA section 4(a)(1)(B)(i).

C. Substantial Production

EPA proposed a value of 1 million pounds as a threshold level for findings of "substantial production." 56 FR 32296. As an alternative to this threshold, EPA solicited comments on the adoption of the TSCA section 5(e) New Chemical Program's exposure-based substantial production threshold (i.e., 220,000 pounds) or some higher threshold (56 FR 32299).

Both CMA and SPI commented that EPA's proposed production threshold is a reasonable interpretation of "substantial production" under TSCA section 4(a)(1)(B) (Refs. 1 and 2). However, according to CMA, "[w]hile EPA's approach is a reasonable one, a production threshold of 2.2 million pounds would be preferable to achieve consistency between EPA's activities under TSCA section 4 and the OECD HPV Existing Chemical Testing Program" (Ref. 1). CMA noted that for "purposes of requiring certain extensive types of studies, EPA also uses 2.2 million pounds as a production volume trigger in its new chemicals program under TSCA section 5" (Ref. 1). HSIA also suggested use of TSCA section 5 trigger for substantial production (Ref. 6). Monsanto (Ref. 3), HSIA (Ref. 6), and ETAD (Ref. 4) also support the adoption of the OECD HPV threshold for the purpose of international harmonization.

EPA disagrees with CMA and HSIA that 2.2 million pounds production is the sole threshold utilized in the TSCA section 5 New Chemicals Program. In general, screening level toxicity studies for human health and/or environmental effects may be required for chemical substances expected to be produced in quantities equal to or greater than 220,000 pounds per year. The New Chemicals Program, as a matter of policy, may specify higher tiered testing (e.g., bioassay, neurotoxicity) under certain circumstances (i.e., use in consumer products) for those chemicals anticipated to be annually produced in amounts of 2.2 million pounds or greater; however, the exposure-based substantial production threshold for considering testing under section 5(e)(1)(A)(ii)(II) is 220,000 pounds (Ref. 16).

EPA disagrees that the OECD HPV threshold would be a more reasonable approach for the initial threshold under TSCA section 4. The OECD HPV threshold was established under different circumstances than the proposed threshold for "substantial production." Eighteen member countries (including all major producing countries) developed national inventories of HPV chemicals manufactured or imported into their countries. These inventories were merged into a comprehensive inventory maintained by the OECD, and is called the OECD Representative List (Ref. 17), which includes all chemicals (excluding polymers and petroleum fractions) reported in any member country in excess of 10,000 tonnes (22 million pounds) and all chemicals reported in two or more countries in excess of 1,000 tonnes (2.2 million pounds). Hence, the OECD HPV production volume threshold of 2.2 million pounds was conceived merely to guide the generation of national inventories which when combined would yield an international list of high production volume chemicals. It was assumed by OECD that the production volume alone would be a sufficient indicator of potential exposure such that the OECD's program on existing chemicals has focused since 1988 on the chemicals found on the OECD Representative List.

The TSCA section 4(a)(1)(B)(i) finding of substantial production is not the sole finding EPA must make to require testing. The threshold of 1 million pounds set forth by EPA in its proposed statement of policy (56 FR 32294) is one of several findings EPA must make before a substance may be subject to testing. EPA must also find that there is substantial release, or substantial or significant human exposure under TSCA sections 4(a)(1)(B)(i)(I) and (II). In addition, EPA must find that data are insufficient and testing is necessary under TSCA sections 4(a)(1)(B)(ii) and (iii). EPA does not believe that a production volume threshold which is chosen to generate an inventory for an international program [illegible]

chemicals and which is the only trigger for entry into that program should be determinative of the threshold chosen for "substantial production" under TSCA section 4(a)(1)(B)(i).

GAF, BASF, and ACC objected to the proposed threshold on two grounds. First, the proposed threshold value will involve subjecting 95 percent of U.S. chemical production (on a total volume basis—11 percent on number of chemicals basis) to potential testing. They argue that because the threshold will encompass such a large percentage of chemical production, the threshold reflects an incorrect interpretation of section 4(a)(1)(B) (Ref. 7).

As previously explained, EPA has broad discretion in defining "substantial" and could choose a quantitative threshold at any point along a wide spectrum when construing the meaning of "substantial production." For instance, if one were to create a chart ranking from lowest to highest the aggregate production for all substances on the TSCA Inventory, EPA could interpret the term "produced in substantial quantities" narrowly to apply only to substances produced in volumes at the extreme top end of the chart. EPA could also choose to adopt a broader interpretation, finding all chemical production to be substantial unless it fell below a value at the extreme low end of the chart.

EPA has proposed a production figure in between the two extremes. The 1 million pound threshold for production narrows the "universe" of chemicals potentially subject to TSCA section 4 testing under TSCA section 4(a)(1)(B) to 11 percent of the TSCA Inventory. Since that small percentage of the Inventory accounts for 95 percent of total chemical production, it is reasonable to use this information as a basis for making a finding of "substantial production" for substances produced in excess of that threshold.

GAF, BASF, and ACC also commented that the 1 million pound threshold "will impose an unfair economic burden on chemical manufacturers and processors that could stifle technological innovation" (Ref. 7). This comment (which is unsupported by any empirical data) also appears to reflect a misunderstanding of the scope of this policy statement.

Neither the "B" policy nor any particular numerical threshold set forth herein constitutes an automatic trigger for testing. Furthermore, this policy statement does not address the amount of testing to be required for chemicals meeting the "B" findings criteria, so it is not possible to determine whether a particular production volume threshold would have any economic impact.

EPA does, however, carefully consider the potential economic impacts and the value of testing data for all section 4 test rules. For each chemical subject to testing, EPA conducts an analysis which estimates the costs of testing. In addition, EPA considers any comments received on the economic effects of proposed testing requirements when developing final rules under section 4, and may revise testing requirements when respondents demonstrate that the rule would impose excessive economic burdens or would stifle technological innovation.

The consideration of economic impacts is particularly important for chemical testing decisions because EPA's purpose in using section 4 is to obtain data for use in risk assessment and, where necessary, risk management activity. EPA recognizes that if the testing it requires on a substance under section 4 imposes an unfair or excessive burden, the likely result of the section 4 rule would be to drive the chemical from the market, rather than to produce test data. To insure that test data are received, EPA must be concerned with any significant adverse economic impacts associated with section 4 test rules. Economic considerations are therefore well integrated into EPA's testing decisions.

In response to EPA's alternative threshold proposal for the substantial production criterion (220,000 pounds) used in the review of new chemical substances under section 5 of TSCA, Callery Chemical Company stated,

> [a]t this threshold production level, the publication of production quantities will not only reveal extremely sensitive confidential business information but will clearly overwhelm the Agency with work that it cannot handle (Ref. 5).

EPA believes that adopting the threshold of substantial production used in the review of new chemical substances under section 5(e) of TSCA is inappropriate at this time, although for different reasons. Callery Chemical Company's concern about public disclosure of sensitive business information is addressed elsewhere in this notice (Unit II.F. of this notice). EPA recognizes that the number of chemicals which could be considered as potential testing candidates under section 4 of TSCA would be greater if the lower threshold value of 220,000 pounds were adopted. However, substantial production is only one of the findings that EPA must make in order to propose chemical testing under section 4 of TSCA. Therefore, there is no reason to believe based on a lower threshold alone that EPA would be overwhelmed, as Callery Chemical Company believes, by adoption of the TSCA section 5 threshold value for substantial production. Nevertheless, for the reasons set forth above and in the proposed policy, EPA will adopt the 1 million pound threshold for "substantial production" under section 4(a)(1)(B)(i) of TSCA.

D. Substantial Release

If the criterion for "substantial production" is met, then at least one of three additional findings under TSCA section 4(a)(1)(B)(i) must also be made before testing is required. The first of these findings is that the substance "enters or may reasonably be anticipated to enter the environment in substantial quantities" under TSCA section 4(a)(1)(B)(i)(I). EPA refers to this finding as "substantial release" and proposed that a value of 1 million pounds per year release or release of 10 percent or more of total production volume, whichever is lower, be established as the threshold value for "substantial release." As an alternative to this threshold, EPA solicited comments on the adoption of a fixed threshold, such as 100,000 pounds or 1 million pounds (56 FR 32296).

CMA, HSIA, and SPI disagree with EPA's interpretation that "enters the environment in substantial quantities" equates with "substantial" release. These commenters contend that EPA must consider not simply the total poundage released but also other factors that address the potential for human and/or environmental exposure such as the chemical's persistence in the environment and its likely or estimated concentrations in various environmental media (Refs. 1, 2 and 6).

EPA disagrees with the commenters' arguments regarding what information EPA must consider when making a finding under TSCA section 4(a)(1)(B)(i)(I). In effect, CMA attempts to import the "exposure" component of clause (II) of section 4(a)(1)(B)(i) into clause (I). However, as indicated by the word "or" between the two clauses, clauses (I) and (II) of section 4(a)(1)(B)(i) can be interpreted as being mutually exclusive. While EPA may, if it chooses, make a finding under both clause (I) and clause (II), a finding under either clause alone, coupled with findings under 4(a)(1)(B)(ii) and (iii), is sufficient to support a test rule.

EPA believes that it is reasonable to interpret section 4(a)(1)(B)(i)(I) to mean that any release during the manufacture, distribution in commerce, processing, use or disposal of a chemical substance

is, per se, "entry" of that substance into the environment, irrespective of the substance's subsequent persistence or concentration in the environment. TSCA explicitly uses different terms, "enters" in clause (I), and "exposure" in clause (II). There is nothing in the statute or legislative history that clearly indicates that clause (I) necessarily embraces or incorporates an "exposure" component, or a durational or persistence requirement. Moreover, in the cumene decision, the Court explicitly rejected CMA's argument that EPA must incorporate a "persistence" component in making a section 4(a)(1)(B)(i)(I) finding. See 899 F.2d at 355–356, and n. 15–16. For these reasons, EPA believes that its interpretation of the phrase "enters the environment" as encompassing any "release" to the environment is a reasonable reading of section 4(a)(1)(B)(i)(I).

CMA also commented that

> EPA should clarify that, as in section 313 of EPCRA, the only releases on which a "B" finding will be based are releases to air or water beyond site boundaries. Releases or transfers to treatment and waste disposal facilities raise entirely different exposure considerations and should not be taken into account in making "B" findings (Ref. 1).

EPA disagrees with CMA's characterization of the scope of the term "release" in EPCRA, and as the Agency is using that term in its interpretation of TSCA section 4(a)(1)(B)(i)(I). Contrary to CMA's assertion, EPCRA does not limit the term "release" only to releases to "air or water beyond site boundaries." Rather, "release" is broadly defined in EPCRA section 329(8), 42 U.S.C. 11049(8), as

> spilling, leaking, pumping, pouring, emitting, emptying, discharging, injecting, escaping, leaching, dumping, or disposing into the environment ***

Similarly, EPCRA section 329(2), 42 U.S.C. 11049(2), defines the term "environment" broadly to include

> water, air, and land and the interrelationship which exists among and between water, air, and land and all living things.

An identical definition of "environment" appears in TSCA section 3(5), 5 U.S.C. 2602(5). The limiting phrase "beyond facility site boundaries" appears only in EPCRA section 313(d)(2)(A), 42 U.S.C. 11023(d)(2)(A). Under this provision of EPCRA, when considering the reasonably anticipated "significant adverse acute human health effects" of a chemical in the context of an Agency decision to list or delist a chemical on the Toxics Release Inventory, the Agency is limited to a consideration of those effects which would occur "at concentration levels that are reasonably likely to exist beyond facility site boundaries as a result of continuous, or frequently recurring releases." This limitation applies only in this instance, and does not apply to or modify any other clause of EPCRA section 313. Therefore, CMA's attempt to limit the scope of the term "release" under EPCRA, and to relate this limitation to releases considered under TSCA, is baseless.

Moreover, neither "release" nor "enters the environment" is defined in TSCA. As explained above, EPA believes that it is reasonable to interpret clause (I) of section 4(a)(1)(B)(i) of the Act to encompass any release of the substance to the environment. For purposes of this policy, and consistent with the definition of "environment" in TSCA, "enters the environment" under section 4(a)(1)(B)(i) includes any releases to "water, air, and land" that result from or may reasonably be anticipated to result from the manufacture, processing, distribution in commerce, use or disposal of a chemical substance or mixture, regardless of the source or nature of the release.

Furthermore, TSCA's scope is not limited to consideration of only releases from a site or transfers to treatment and waste disposal facilities. Rather, TSCA is intended to broadly address the general uncertainty about the effects of the manufacture, processing, distribution in commerce, use or disposal of a chemical substance or mixture.

SPI commented that EPA's proposed 1 million pound release threshold, and the proposed alternative 10 percent of production volume threshold, were "arbitrary" and that "EPA does not provide any support for the selection of 10 percent of the production volume other than it would seem to be a sizable number. Absent any frame of reference such as exposure, or presence in the environment, such a number is no less valid than 1 percent or 60 percent" (Ref. 2).

EPA disagrees with SPI's comment. In choosing the 1 million pound threshold value to represent "substantial" release, EPA was guided by the same considerations that were used to determine the threshold value for "substantial" production. In choosing the poundage threshold, EPA used the Toxics Release Inventory (TRI) in judging the "substantial" nature of that amount of release. EPA has determined that 37 percent of the chemicals listed on the TRI have releases of over 1 million pounds and that these releases account for 99 percent of the total reported release on the TRI by volume. Clearly, the small percentage of TRI chemicals that exceed the selected poundage threshold accounts for the vast majority of total TRI releases. It is reasonable for EPA to use that information as a basis for focusing its attention on chemicals released in excess of that threshold.

In addition, as stated in the proposed policy statement (56 FR 32296), the percentage threshold has been proposed because EPA is also concerned about chemical releases that are a sizable percentage of the production volume of that chemical. EPA believes that when such a sizable percentage of a chemical's production volume is released, that release should be considered "substantial" for that chemical substance. This threshold will allow EPA the flexibility to require testing of chemicals with production volumes equal to or greater than 1 million pounds per year, but with releases of less than 1 million pounds per year.

E. Substantial and Significant Human Exposure

EPA proposed that "substantial exposure" means exposure to large numbers of people (56 FR 32297), and set out the following numerical thresholds for a finding of "substantial exposure": 1,000 workers, 10,000 consumers, and/or 100,000 persons in the general population. EPA proposed that "significant exposure" refers to the nature of the exposure. A finding of "significant exposure" would generally be made where the numerical threshold for numbers of persons exposed for "substantial exposure" is not met, but the nature of the exposure is sufficiently direct, large or prolonged. However, EPA may make a finding that there is or may be both significant human exposure and substantial human exposure, if the number of people exposed exceeds the thresholds set forth in this policy and the nature of the exposure is also significant as set forth in this policy. As an alternative to these thresholds, EPA solicited comments on the adoption of either the TSCA section 5(a) New Chemical Program's exposure-based criteria for "substantial" and "significant" human exposure or some other criteria for which there is a strong basis or supporting rationale (56 FR 32299–32300).

OSHA and NIOSH submitted comments supportive of EPA's statement of policy for determining "substantial" and "significant" human exposure. In fact, NIOSH urges EPA to seriously consider its alternative

proposal*** that would result in testing compounds for which fewer than 1,000 workers are exposed" (Ref. 9). OSHA agreed with EPA that, for TSCA purposes, the proposed definitions for "substantial" human exposure and "significant" human exposure set reasonable criteria for determining if testing is required when toxicity data are absent or incomplete. Accordingly, "OSHA believes that exposure of 1,000 workers to a chemical of unknown toxicity represents adequate impetus to require testing" (Ref. 8). In addition, OSHA stated that the proposed distinction between "substantial" human exposure and "significant" human exposure is appropriate (Ref. 8).

1. *Substantial human exposure.* CMA, SPI, Monsanto, ETAD, HSIA, GAF, BASF, and ACC submitted comments that questioned the definitions and rationale underlying the proposed criteria. A common comment was that EPA had not provided sufficient rationale to justify the proposed numerical thresholds for determining "substantial" human exposure.

EPA disagrees with the commenters' suggestion that EPA did not provide sufficient rationale for the numeric thresholds chosen to guide "substantial" human exposure findings. As articulated in the proposed policy statement (56 FR 32297), EPA chose numeric thresholds to characterize "substantial" human exposure because it is EPA's belief that TSCA section 4(a)(1)(B) was intended to address situations where large numbers of people may be exposed to a chemical substance and little or no hazard data exists to indicate whether or not that chemical substance may present an unreasonable risk. EPA has based its thresholds for workers on experience gained through case-by-case analysis of existing substances. Furthermore, according to the National Occupational Exposure Survey (NOES) data (Ref. 18), an average of 650 workers are potentially exposed to a chemical substance produced in a quantity of 1 million pounds. In other words, for a chemical produced in a quantity of 1 million pounds, it is relatively uncommon that as many as 1,000 workers would be exposed. Given this analysis and its experience of case-by-case analysis of existing chemical exposure over the years, EPA believes that it has reasonably interpreted "substantial human exposure" under TSCA section 4(a)(1)(B)(i)(II) by utilizing a relatively conservative threshold of exposure of 1,000 workers to a chemical substance. Moreover, although many respondents do not favor EPA's rationale for making a determination of substantial human exposure, they did not specifically argue that these thresholds were unreasonable, nor did they provide any specific alternative criteria or rationale.

The different numeric thresholds for worker, consumer, and general population exposure are EPA's attempt to reflect the inherent differences in the probable exposure scenarios for particular categories of individuals. As stated in the proposed policy statement, "workers generally are exposed on a more routine or direct basis than consumers, and consumers are generally exposed on a more direct basis than the general public" (56 FR 32297, July 15, 1991). EPA has decided to apply a differential equal to one order of magnitude between the worker, consumer, and general population thresholds. EPA believes this approach is reasonable and sufficiently reflects the inherent differences in the probable exposure scenarios for each of the categories of individuals. Both OSHA (Ref. 8) and NIOSH (Ref. 9) supported the basis for the distinction between substantial exposure to workers, consumers, and the general population. EPA recognizes that this approach, which is consistent with the Fifth Circuit's cumene decision, integrates to some extent the concepts of "substantial" and "significant" in determining what constitutes "substantial" human exposure. 899 F.2d at 356, n. 17 (cumene decision); and 56 FR 32297–32298 (July 15, 1991).

Although commenters generally criticized EPA's rationale for choosing the numeric thresholds articulated in the proposed policy statement, none of the comments offered any specific alternative thresholds for making a section 4(a)(1)(B)(i)(II) finding. Many comments expressed the view that EPA must consider certain chemical specific factors to make a "substantial" human exposure finding.

CMA and other commenters objected to EPA's threshold approach for determining "substantial" exposure because it is based solely on numbers of people exposed and does not take into account the physical and biological properties of a chemical, the manner of its use and release, the level, frequency, and duration of exposure, nor any available relevant exposure data. CMA argues that EPA should "make prudent but realistic assumptions about the exposure levels that would be of regulatory concern if testing demonstrates adverse effects" (Ref. 1).

EPA believes that CMA's comments reflect an inaccurate understanding of the role of chemical testing conducted under the authority of section 4 within TSCA's statutory framework and purposes. As explained above in Unit I., TSCA was enacted to ensure that, given the exposure of humans and the environment to a large number of chemical substances and mixtures with potentially harmful effects, there would be effective regulation of commerce in such substances. TSCA section 2(a), 15 U.S.C. 2601(a). Since the potential effects of many chemical substances in commerce are not known, the policy provisions of TSCA reflect Congress' intent that:

> adequate data should be developed with respect to the effect of chemical substances and mixtures on health and the environment and that the development of such data should be the responsibility of those who manufacture and those who process such [substances].

TSCA section 2(b)(1), 15 U.S.C. 2601(b)(1). Section 4 of TSCA provides EPA the authority to require such testing.

In effect, by urging EPA to make "assumptions about the exposure levels that would be of regulatory concern if testing demonstrates adverse effects," CMA argues that EPA must make an affirmative finding that a chemical substance would pose an unreasonable risk of injury at some hypothetical levels of toxicity and exposure in order to require testing under section 4(a)(1)(B) of TSCA. This contention was explicitly rejected by the Court in the cumene decision, 899 F.2d at 354–355.

Further, in contrast to the TSCA section 4(a)(1)(A) risk-based criterion and the TSCA section 6 risk/benefit analysis, a finding under TSCA section 4(a)(1)(B) requires no risk analysis. See 899 F.2d at 354 (cumene decision); and 859 F.2d at 979, and 984–988 (EHA decision). Additionally, as both exposure and hazard are factors used to determine whether a chemical may pose a risk, without the necessary hazard information, making "prudent but realistic assumptions about the exposure levels that would be of regulatory concern if testing demonstrates adverse effects" would be a meaningless exercise. The utility of the frequency, duration, and levels of exposure is limited when EPA is acting in the absence of information about the hazard of the chemical substance in question. Given the statutory framework of TSCA, its legislative history, and the case law interpreting the section 4 testing provisions, EPA does not believe that it is required to undertake the type of detailed exposure analysis urged upon it by CMA and other respondents in making the TSCA section

4(a)(1)(B)(i)(II) "substantial" human exposure finding.

Although EPA is not required to consider the factors enumerated above in making a finding of "substantial" human exposure, EPA did, as a matter of policy, offer for consideration in the proposed policy statement an alternative set of human exposure criteria, based on the TSCA section 5(e) New Chemicals Program human exposure guidelines, which incorporated some of these factors (56 FR 32299–32300, July 15, 1991). However, despite an explicit invitation for comments addressing the merit and feasibility of applying these guidelines in the context of section 4 test rules, none of the comments addressed the specific numerical values and other factors outlined in EPA's proposed alternative thresholds. Comments on the alternative thresholds expressed only the general view that the section 5(e) criteria should not be applied to review of existing chemicals under section 4(a)(1)(B). (Refs. 1 and 2). Furthermore, EPA solicited comments on adopting "some other criteria than the criteria proposed herein by EPA" and "the supporting rationale" for such criteria, yet received no comments offering any alternative thresholds or other specific suggestions or rationales.

Despite EPA's attempt to elicit more specific comments, most commenters addressed only the general concept of the proposed thresholds. For example, CMA argued that "Congress clearly expected EPA to demonstrate a pattern of unusually large or widespread exposure which differentiates the test substance from typical chemicals in commercial use" (Ref. 1). Based on this argument, CMA suggested that EPA develop an analysis of variations in human exposure potential within the universe of commercially produced chemicals. Such an analysis would provide a basis for "low", "medium", and "high" exposure chemicals. For example, CMA stated that EPA had made no effort to determine whether there are many or few chemicals to which at least 1,000 workers are exposed. Without such an analysis, CMA argued, one cannot conclude that exposure to 1,000 workers is large or small for typical chemicals in commercial production.

CMA suggested that data exist which could be used to make order-of-magnitude distinctions regarding the number of workers and consumers exposed to different chemicals. Data sources suggested by CMA include the NOES; information collected under the TSCA section 8(a) Preliminary Assessment Information Rule (PAIR); the Household Solvent Products: A National Usage Survey, EPA/OTS 560/5–87–005; and the System for Tracking the Inventory of Chemicals (STIC) Database, U.S. Consumer Product Safety Commission (CPSC) 1988. CMA also stated that about 400 substances have been screened under TSCA section 4 and that EPA's RM1 (Risk Management-1) process has resulted in a systematic review of available exposure information for a growing number of existing chemicals (Ref. 1).

As explained above, EPA disagrees with commenters' fundamental premise that the Agency is required to undertake an analysis of typical exposures of all chemical substances currently in commercial production in order to support its interpretation of the term "substantial" under section 4(a)(1)(B)(i)(II) of TSCA, or that such an approach was mandated by Congress. Neither the plain language of TSCA nor the legislative history require EPA to undertake the kind of exhaustive analysis urged upon it by CMA and other respondents to support findings under TSCA section 4(a)(1)(B)(i). In short, the cost of generating the exposure information necessary for this type of analysis may well exceed the cost of testing, and is not appropriate for a decision to require testing under section 4 of TSCA.

EPA notes, however, that it does not ignore all of these factors in making decisions to require testing under section 4 of TSCA. For each substance-specific rulemaking under section 4, EPA must determine whether there is sufficient "data and experience" upon which to "reasonably determine or predict" the health and environmental effects of a chemical substance, and whether testing of such substance is "necessary to develop such data." In making these determinations, the Agency has always, and will continue to examine all available and relevant information concerning the substance in question, including the physical and biological properties of the substance, the manner of its use and release, the level, frequency, and duration of exposure, and any available relevant exposure and toxicity data. It is the responsibility of interested parties to provide any information they believe may be relevant to the Agency's determination to require testing of a particular chemical substance under TSCA section 4. Consequently, EPA always welcomes the submission of such information during the notice and comment period provided prior to the promulgation of any final test rule.

Furthermore, even if EPA were to conduct the analysis urged upon it by CMA at this time, the potential sources of information identified by CMA present a number of problems for such an analysis due to the limited scope of their coverage. These limitations differ from database to database, and include the number of chemicals covered, limited overlap between the databases, the specific data included in each database or information source, imprecise data concerning current production of a given substance, gaps in exposure, use and release information, and differences in the quality of data and the basis for each estimated parameter. For example, the NOES database developed by NIOSH contains information on more than 4,000 chemicals. This database contains useful information on the approximate number of workers potentially exposed, the number of female workers potentially exposed, the approximate number of facilities in the industry handling the chemical, and the industry Standard Industrial Code (SIC) where the chemical is found. However, by itself, the database is insufficient to fully characterize the potential worker exposures because the database does not contain information of the frequency, duration, or the levels of workers' exposures. Due to these limitations, EPA does not believe that it is possible to develop an analysis of the variations in human exposure potential for the entire universe of chemicals. However, in the context of a substance-specific rulemaking, EPA will carefully consider the human exposure scenario. Once again, EPA invites interested parties to submit for EPA's consideration all available and relevant information during the notice and comment period for each substance-specific rulemaking under TSCA section 4.

2. *Significant human exposure.* CMA, supported by SPI, agreed with EPA that "exposure can be considered 'significant' where the potential exposed population is not large but the conditions of exposure are unique and create unusually great concern about the substance's potential for adverse effects" (Refs. 1 and 2). OSHA also agreed and stated,

> [i]f a worker is exposed directly (i.e., by inhalation) or on a routine or episodic basis, it is reasonable to determine that a significant human exposure exists, even if fewer than 1000 workers are exposed (Ref. 8).

However, CMA, HSIA and others commented that EPA's proposed policy does not "meaningfully identify where such 'significant' exposures might exist" (Ref. 1).

EPA does not believe that it has, at this time, sufficient experience to

generically define criteria that it will employ in making a finding of "significant" human exposure under TSCA section 4(a)(1)(B)(i)(II). Should EPA make such a finding in a substance-specific rulemaking, it will fully explain the bases for that finding at that time.

CMA also stated that EPA has not adequately defined or explained the term "direct exposure" and how it relates to "significant" exposure (Ref. 1).

A "direct" exposure may be characterized as having a clearly identifiable or likely source of the chemical, an exposure pathway from the source to the receptor that can be expected, with reasonable certainty, to result in the potential for exposure, and an exposure route that will or can reasonably be expected to result in intake/uptake by the receptor. For these reasons, it is reasonable to conclude that in instances where exposure is "direct", EPA may consider the exposure to be "significant" under TSCA section 4(a)(1)(B)(i)(II).

GAF, BASF, and ACC stated that EPA has failed to establish a clear distinction between "substantial" and "significant" exposure as presented in Table 1 of the proposed policy (Ref. 6).

As previously acknowledged, there is some overlap between the criteria used to construe "substantial" and "significant" human exposure. However, it is EPA's belief that such an overlap is not inconsistent with the statutory purpose and legislative history of TSCA. As stated in the cumene decision, 899 F.2d at 356, n. 17, "it is not necessarily clear that "significant" and "substantial" as used in clause (II) must be understood in a way that prevents any overlap."

CMA recommended that "EPA should judge the "significance" of exposure by examining whether, for the affected population, it involves large concentrations or is usually frequent or prolonged" (Ref. 1). HSIA suggested that EPA consider "the mode of manufacture of the chemicals, the manner of use, and physical properties which may make even quite direct exposure to the threshold levels of little or no concern" (Ref. 6). To accomplish this evaluation, CMA recommended that "EPA should develop representative exposure scenarios for workers, consumers and the general population. These scenarios should then be used to identify workplace operations, consumer products or environmental releases with uncommonly large exposure potential" (Ref. 1).

Because the determination of what is "significant" human exposure can be very chemical and use specific, EPA does not believe that the representative exposure scenarios suggested by CMA would have much utility. However, EPA will examine, among other factors, the criteria suggested by CMA and others in the context of substance-specific rulemakings under TSCA section 4, including the manner of use, the chemical specific physical properties, and whether for the affected population the exposure would involve large concentrations or is frequent or prolonged. Also, in response to an earlier suggestion from commenters, EPA did propose, as an alternative to the proposed section 4(a)(1)(B) criteria for "significant" exposure, adopting the qualitative and quantitative "substantial" and "significant" exposure guidelines used to review new chemical substances under section 5(e) of TSCA (56 FR 32299). These TSCA section 5(e) criteria do include some consideration of frequency, duration and magnitude of exposure for workers, and consideration of magnitude of exposure for the general population. The section 5(e) criteria for consumer exposure are qualitative only. These criteria were developed based on experience assessing the exposures associated with thousands of new chemicals with limited, but known, uses and exposure settings. However, as explained above, none of the commenters were in favor of EPA adopting the TSCA section 5(e) human exposure criteria.

In summary, for the purpose of determining whether there is or may be "substantial" exposure under TSCA section 4(a)(1)(B)(i)(II), EPA will utilize the numerical thresholds of 1,000 workers, 10,000 consumers, and/or 100,000 persons in the general population. A finding of "significant" exposure will generally be made on a case-by-case basis, taking into consideration, among other factors, the manner of use, substance specific physical properties, concentration levels, and the duration and frequency of the exposure to the substance. It is important to note that TSCA section 4 is an information gathering tool only and that it places no limits on a chemical substance's manufacture, processing, distribution in commerce or use. Given the limited purpose of TSCA section 4(a), to require testing, and because the finding that there is or may be "substantial" or "significant" human exposure is only one of several findings EPA must make to require testing, EPA believes that the criteria set forth herein are a reasonable interpretation of the phrase "significant or substantial human exposure" in TSCA section 4(a)(1)(B)(i)(II).

F. Other Issues

1. *Categories.* EPA proposed that it would apply the generic numerical thresholds for most substances considered for action under TSCA section 4(a)(1)(B). In some cases, however, where the thresholds are not met, EPA proposed that it may consider "additional factors" on a case-by-case basis for making findings. An example of such a case mentioned by EPA in the proposed policy was chemical categories.

CMA, supported by SPI, believes that categories should be narrowly defined.

> In CMA's judgement, the only category that would be suitable for a 'B' finding would be one whose members possessed similar chemical structures and were therefore likely to have closely related health or environmental effects (Ref.1).

CMA also comments that representatives from a category could be selected for testing, obviating the need to test each and every member of the category.

EPA does not agree with the commenters that categories must, by necessity, be limited to chemicals with similar structures or toxicological properties. However, EPA does agree that chemicals with similar structures or toxicological properties could, in certain instances, be grouped together and referred to collectively as a category. Additionally, after consideration of all relevant chemical specific parameters, EPA may propose category findings on a case-by-case basis, and will solicit comments on this decision in the specific proposed test rule. This is the approach taken in the proposed test rule for glycidols (56 FR 57144, November 11, 1991).

2. *Additional or mitigating factors.* CMA, Monsanto and others stated that EPA should, in implementing its policy under section 4(a)(1)(B) of TSCA, preserve the flexibility to consider additional and mitigating factors on a case-by-case basis. Monsanto supports the "substantial" and "significant" exposure criteria as benchmarks but believe that other factors, on a case-specific basis, may need evaluation. For example, CMA stated that where there are no other indicators of substantial exposure other than that a chemical appears in human adipose tissue, EPA should consider that the tissue may be reflective of background levels in the environment, a metabolic product of another compound, or release from non-industrial sources (Ref. 1). In such a situation, CMA suggests that testing under section 4(a)(1)(B) of TSCA would not be justified.

EPA agrees with the respondents that in implementing this policy, EPA should preserve the flexibility to consider certain variables on a case-by-case basis. Furthermore, in implementing section 4(a)(1)(B) of TSCA, EPA intends to use the criteria articulated in this policy statement as guidelines to retain the flexibility to consider all relevant variables in making findings under section 4(a)(1)(B) of TSCA. As stated in the proposed statement of policy, EPA intends to utilize the generic thresholds for most chemical substances considered for action under TSCA section 4(a)(1)(B). In some cases, however, where the thresholds are not met, EPA may consider "additional factors" on a case-by-case basis to make findings.

EPA's authority to use this flexible approach was recognized by the Court in its decision regarding the cumene test rule. The Court stated that EPA's definition need not be precise — it need not "function like a mathematical formula." 899 F.2d at 359. On the other hand, there may be some instances when a chemical substance meets the criteria articulated under TSCA section 4(a)(1)(B)(i), but where testing under TSCA section 4(a)(1)(B) will not be required because EPA finds under subsection (ii) or subsection (iii) of section 4(a)(1)(B), respectively, that data are sufficient to reasonably determine or predict the effects of the manufacture, process, distribution, use, or disposal of the chemical or that testing is not necessary. Monsanto, GAF, BASF, and ACC strongly support the use of "mitigating factors" to justify not requiring testing for those chemicals that meet the section 4(a)(1)(B)(i) criteria for which the available data are sufficient to reasonably determine or predict the effects of the manufacture, process, distribution, use or disposal of the chemical and/or that testing is not necessary.

3. *Confidential business information.* Callery Chemical Company is concerned that an EPA finding under TSCA section 4(a)(1)(B)(i) that a chemical may be produced in substantial quantities may result in disclosure of confidential business information (CBI) and "could provide valuable marketing information to competitors and potential competitors without justification" (Ref. 5).

EPA does not believe that disclosing to the public the fact that at least 1 million pounds of a chemical substance or mixture is produced per year would be a disclosure of CBI. In making such a finding, EPA would be relying on the aggregate production volume for all manufacturers of the substance. Thus, EPA would not be disclosing specific information regarding any particular manufacturer's production. Should such a statement affect a single manufacturer, as might be the case with specialty chemicals, EPA does not believe that a statement that production volume is at least 1 million pounds would disclose sufficient information to be considered a disclosure of information which might be entitled to confidential treatment. Furthermore, TSCA section 14(a)(4) authorizes the disclosure of information which otherwise might be entitled to confidential treatment when relevant in any proceeding under TSCA, including rulemaking, provided that disclosure is made in such a manner as to preserve confidentiality to the extent practicable without impairing the proceeding. See 40 CFR 2.306 (1991). EPA believes that by disclosing only that a substance is or will be produced in volumes of 1 million pounds per year or greater, confidentiality would be preserved to the extent practicable while still making findings under section 4(a)(1)(B). However, EPA will make this decision on a case-by-case basis, in accordance with 40 CFR 2.306, if such situations arise.

G. Beyond Scope

Respondents raised several issues which are beyond the scope of this policy statement. The issues relate to the use of structure activity relationships (SAR), exclusion of polymers, tiered testing schemes, and testing priorities under TSCA section 4(a)(1)(B).

1. *Structure activity relationships.* Monsanto believes that "[t]he 'B' policy should recognize and authorize the use of structure activity relationships (SAR) when evaluating the testing needs and priorities for substantial production chemicals" (Ref. 3). Monsanto commented that a large number of their high production volume chemicals are produced as intermediates and then later converted to neutral salts to facilitate handling and shipping; in most of these cases, the salt and intermediate itself have essentially the same toxicological priorities. Therefore, by testing and evaluating one substance, the other chemical can be evaluated using SAR.

Monsanto's comment is not relevant to a discussion of TSCA section 4(a)(1)(B)(i). Rather, whether SAR will be a factor in determining the "testing needs and priorities for substantial production chemicals," is a matter relevant to TSCA section 4(a)(1)(B)(ii) and (iii) findings. Therefore, Monsanto's concerns would be addressed in relation to a chemical specific test rule.

2. *Polymer exclusion.* Monsanto commented that polymer exemptions should be recognized by EPA under this policy, because "[p]olymers represent a special class of chemical substances that needs separate consideration under the proposed 'B' policy" (Ref. 3). Monsanto noted that a number of polymer substances are biologically benign and, therefore, do not represent substantial health or environmental concern. In support of this position, Monsanto noted that exemption procedures are provided for in the review of new chemical substances under TSCA section 5. Likewise, the OECD HPV program did not include polymers on the Representative List. Monsanto believes a similar type of polymer exemption should be offered under the section 4(a)(1)(B) policy.

Again, Monsanto's concerns relate more to a discussion regarding TSCA section 4(a)(1)(B)(ii) and (iii) than TSCA section 4(a)(1)(B)(i). EPA believes that in the absence of any submitted data, it is difficult to address the manufacturers' concern. Polymers do not have a well-defined composition, and there may be a need to test some lower molecular weight polymers or oligomers which may have potential for health or environmental effects. Therefore, it would be premature for EPA to suggest that a blanket exemption from testing for polymers may be appropriate. To date, EPA has not proposed or required testing of a polymeric compound under TSCA.

3. *Tiered testing.* Monsanto commented that EPA should adopt a tiered testing approach to evaluating chemical substances.

EPA believes that determination of whether tiered testing is appropriate generally must be made on a case-by-case basis. EPA recognizes that incorporating a tiered testing scheme in a test rule can generate preliminary data relatively quickly with minor expense. However, for a relatively well characterized chemical substance, it is likely that a tiered testing approach would not be appropriate. In other instances, if the scientific literature contains information which strongly suggests that the chemical is used in a way that would result in widespread worker or consumer exposure (e.g., a solvent use), then it is less likely that a preliminary experiment would return the kind of data to support the definitive answer needed for such widespread exposure. Thus, automatic incorporation of a tiered testing scheme may result in the performance of screening studies which are unlikely to provide the needed information

4. *Testing priorities.* CMA commented that, in addition to adopting the 2.2 million pound threshold for substantial production, EPA should adopt a tiered, sequential process for identifying data needs on all high production volume (HPV) chemicals. In CMA's opinion, EPA should group HPV chemicals into categories and establish priorities for the review of each chemical.

Once overall testing priorities have been set, individual high volume chemicals should be reviewed to determine whether they warrant an initial set of screening tests comparable to those in the OECD Screening Information Data Set (SIDS) battery (Ref. 1).

EPA clearly articulated in the proposed statement of policy and in Unit I. of this final notice that issues related to how EPA establishes testing priorities and how EPA makes findings under subsections (ii) and (iii) of section 4(a)(1)(B) of TSCA would not be addressed in this statement of policy. If at some future point in time, EPA decides that adoption of a testing program such as that proposed by CMA would be beneficial in the gathering of data on existing chemical substances, EPA will clearly articulate that policy and the underlying rationale in a notice.

III. Final Policy

A. Substantial Production

EPA is establishing a threshold value of 1 million pounds, aggregate production volume of the substance per year for all manufacturers, as the substantial production threshold. This threshold currently represents only 11% of the entire universe of chemical substances potentially subject to testing under TSCA section 4, yet accounts for 95% of total chemical production by volume. For the reasons articulated in the proposed statement of policy (56 FR 32294) and Unit II.C. of this notice, EPA believes a threshold value of 1 million pounds is a reasonable interpretation of the phrase "produced in substantial quantities" in TSCA section 4(a)(1)(B)(i).

B. Substantial Release

EPA is establishing a threshold value of 1 million pounds of release to the environment from all sources per year; or release equal to or greater than 10 percent of production volume per year, whichever is lower, as the threshold for substantial release. In choosing the 1 million pound threshold value to represent "substantial" release, EPA used the TRI as a guide in judging the "substantial" nature of that amount of release. EPA has determined that 37 percent of the chemicals listed on the TRI have releases of 1 million pounds or greater and that these releases represent over 99 percent of the total reported release on the TRI by volume. Clearly, the small percentage of TRI chemicals that exceed the poundage threshold accounts for the vast majority of total TRI releases.

The percentage threshold reflects EPA's concern about chemical releases that are a sizable percentage of the production volume of that chemical. EPA believes that when such a sizable percentage of a chemical's production volume is released, that release should be considered "substantial" for that chemical substance. For the reasons articulated in the proposed statement of policy (56 FR 32294) and in Unit II.D. of this notice, EPA believes that this is a reasonable interpretation of the phrase "enters the environment in substantial quantities" in TSCA section 4(a)(1)(B)(i)(I).

C. Substantial and Significant Human Exposure

EPA is establishing the criteria in Table 1 of this Unit for "substantial" and "significant" exposure. As articulated in the proposed policy statement, EPA chose numeric thresholds to characterize "substantial" human exposure because it is EPA's belief that TSCA section 4(a)(1)(B) was intended to address situations where large numbers of people may be exposed to a chemical substance and little or no hazard data exists to indicate whether or not that chemical substance may present an unreasonable risk. EPA based its thresholds for workers on experience gained through case-by-case analysis of existing chemicals.

The different numeric thresholds for worker, consumers, and general population are EPA's attempt to reflect the inherent differences in the probable exposure scenarios for particular categories of individuals. EPA decided to apply a differential equal to one order of magnitude between the worker, consumer, and general population thresholds. For the reasons articulated in the proposed statement of policy (56 FR 32294) and Unit II.E. of this notice, EPA believes that these criteria are a reasonable interpretation of the phrase "significant or substantial human exposure" in TSCA section 4(a)(1)(B)(i)(II).

TABLE 1.— TSCA Section 4(a)(1)(B)(i) Human Exposure Criteria Guidelines

Category	Substantial	Significant
General population ...	100,000 people	< 100,000 people population exposed more directly or on a routine or episodic basis.
Consumers	10,000 people	< 10,000 people exposed more directly or on a routine or episodic basis.
Workers	1,000 workers	< 1,000 workers exposed more directly or on a routine or episodic basis.

D. Additional Factors

EPA will apply the generic numerical thresholds for most substances considered for testing under TSCA section 4(a)(1)(B). In some cases, however, where the thresholds are not met, it may be more appropriate to use a case-by-case approach for making findings by applying other considerations. For the reasons articulated in the proposed statement of policy (56 FR 32296) and Unit II.F.2. of this notice, EPA may consider "additional factors" for making findings for substances which do not meet the numerical thresholds articulated herein for evaluating existing chemicals under TSCA section 4(a)(1)(B).

Conversely, EPA may not require testing under TSCA section 4(a)(1)(B) for a chemical that meets the section 4(a)(1)(B)(i) criteria if EPA finds, under sections 4(a)(1)(B)(ii) and (iii), that data are sufficient to reasonably determine or predict the effects of the manufacture, process, distribution, use and disposal of the chemical and/or that testing is not necessary.

IV. Final Test Rule for Cumene

A. Response to Cumene Panel

On July 27, 1988 (53 FR 28195) EPA promulgated a final rule requiring manufacturers and processors of cumene to perform health and environmental effects testing in response to the Interagency Testing Committee's (ITC) recommendation that cumene be given priority testing

consideration under TSCA section 4. Based on the available data, EPA found under TSCA section 4(a)(1)(B)(i) that cumene is "produced in substantial quantities and that it enters the environment in substantial quantities, with the potential for resulting substantial human exposure to cumene from its manufacture, processing, use and disposal." EPA also made the requisite findings under TSCA section 4(a)(1)(B)(ii) and (iii) (53 FR 28200, July 27, 1988). EPA's findings were challenged by the Chemical Manufacturers Association in *CMA v. EPA*, 899 F.2d 344 (5th Cir. 1990). The Court remanded the rule requiring EPA to:

> articulate the standards or criteria on the basis of which it found the quantities of cumene entering the environment from the facilities in question to be "substantial" and the human exposure potentially resulting to be "substantial."

899 F.2d at 360. The Court further instructed EPA to:

> articulate whether its respective [TSCA section 4(a)(1)(B)(i)] clause (I) and clause (II) findings [in the cumene rule] each constitute, alone, an independent and sufficient basis for its testing requirements, or whether, on the other hand, its testing requirements rest only on the clauses (I) and (II) findings jointly ***. The EPA shall further indicate whether its findings under either clause (I) or clause (II) are to any extent dependent on its finding, which we have disapproved, concerning entry into the aquatic environment; and, if so, shall reconsider its clause (I) and (II) findings in the light of our referenced ruling.

Id. at 360, n. 22. Finally, the Court directed EPA to consider new studies to be presented by CMA on remand "unless they would not be material to any of the EPA's criteria relied on for the testing." Id. at 360–361. On remand the Cumene Panel of CMA submitted both specific studies and general comments on the cumene final test rule. The test rule remained in effect, and test data was submitted to EPA in response to the rule.

EPA has addressed some of the Court's instructions concerning EPA's statutory authority and the Cumene Panel's generic comments regarding the "B" policy (Ref. 12) in Unit II. of this notice. Specific comments on cumene and EPA's review of remand evidence are addressed in this Unit IV.

B. Substantial Production

In support of its final test rule, EPA found that cumene is produced in substantial quantities, based on reported U.S. cumene production of 3.35 billion pounds with an additional 339 million pounds imported. This figure was not disputed. For the reasons discussed in Unit II.C. of this notice, EPA believes that this level of production clearly qualifies as "substantial production" under section 4(a)(1)(B)(i) of TSCA. The level of cumene production reported in the final rule well exceeds the "substantial production" threshold articulated in this notice.

C. Substantial Release

In support of the final test rule, EPA found that cumene is released to the environment in substantial quantities based on an estimated 3 million pounds per year of fugitive emissions of cumene to the atmosphere from manufacturing, processing, and use activities. The Court upheld the validity of EPA's estimate. 899 F.2d at 352–353. To a lesser extent, EPA also noted in the final rule that cumene was released in unspecified quantities to the aquatic environment. Because EPA was unable to estimate with reasonable certainty the magnitude of this release, EPA did not rely on this release in calculating human exposure; nonetheless, EPA did believe that there was a potential for human exposure as a result of release of cumene to aquatic environments. The Cumene Panel commented that EPA lacks an adequate basis for finding that cumene "enters the environment in substantial quantities." Specifically, the Panel disagreed with EPA's equating "substantial release" with "enters the environment in substantial quantities." The Panel stated,

> [t]he Agency has made no effort to analyze the extensive evidence in the record regarding the persistence and distribution of cumene in the environment or to relate cumene release levels to human exposure patterns (Ref. 12).

As discussed in Unit II.D. of this notice, EPA rejects the premise that "enter the environment in substantial quantities," as used in section 4(a)(1)(B)(i)(I) of TSCA, be defined to include a determination of "persistence in the environment of those substantial quantities." The Court in the cumene case, 899 F.2d at 355–356, found that EPA is not obliged to follow CMA's construction of TSCA section 4.

The Panel also raised this issue in their comments on the final rule for cumene, asserting that, considering the short half-life of cumene in the atmosphere, there is no reason to believe that, except for populations very close to the plant, there is any general population exposure to cumene. EPA responded that the half-life of cumene in the atmosphere appears to be on the order of 1 or 2 days. At this rate of removal, the cumene emissions from ongoing manufacturing and processing activities would be expected to be distributed over a large portion of the communities near manufacturing and processing facilities depending on the prevailing atmospheric conditions. Thus, the Panel has not provided EPA with a convincing rationale to refute EPA's finding that cumene "enters the environment in substantial quantities" or that there is not "substantial human exposure." Rather, the Panel has only demonstrated that persistence, one of many chemical-specific parameters EPA considers in evaluating a chemical, may be of limited importance when considered with other factors, such as the manufacturing and processing scenario.

D. Substantial Human Exposure

The Panel commented that, even if the release of cumene could be equated to "substantial" environmental entry, EPA would not be justified in requiring human health effects testing unless it were to make a finding of "substantial human exposure."

Once again, the Panel is attempting to link the type of testing required to the bases for the TSCA section 4(a)(1)(B)(i) finding. EPA does not believe this to be a valid interpretation of section 4(a) of TSCA. Furthermore, EPA believes, as stated in Unit II.B. of this notice, that clauses (I) and (II) of TSCA section 4(a)(1)(B)(i) can be interpreted as independent. In particular, although EPA made findings for cumene under both clauses (I) and (II), EPA believes a finding under either clause alone constitutes an independent and sufficient basis for the testing required.

In support of its final rule, EPA found that there may be substantial human exposure to cumene based on the exposure potential to approximately 13.5 million people living in the vicinity of cumene manufacturing and processing facilities. EPA believes that a majority of the people would be exposed as a result of fugitive emissions of cumene to the atmosphere. The majority of cumene manufacturing and processing facilities are concentrated in a few large metropolitan areas. The Court in the cumene case, 899 F.2d at 353, found that the rulemaking record adequately supported EPA's finding. However, when CMA briefed its case, it submitted a monitoring study, not previously submitted as comments on the rule, that relates to the presence of many chemicals, including cumene, in the Houston Ship Channel area [Ref. 19].

The Cumene Panel maintains that the information contained in this study is sufficient to show that EPA cannot make

either the "enters the environment in substantial quantities" or "substantial human exposure" findings of section 4(a)(1)(B)(i).

The remand evidence presented by the petitioners indicates that such exposure does not exist because cumene levels are not elevated even at short distances from the cumene plants (Ref. 12).

As instructed by the Court on remand, EPA has reviewed the study submitted by CMA. In general, EPA's review (Ref. 20) concluded that the study supports the conclusions of its authors. However, the study cited by the Cumene Panel does not show, nor was it designed to show, the monitored environmental concentration from manufacturing and processing facilities. The study's introduction states:

[t]he underlying goal of the monitoring program is to provide member firms with accurate ambient air quality measurements and technical data for better understanding air quality concerns in the Houston Ship Channel area (Ref. 19).

There are seven sites where monitoring devices are maintained downwind from the Houston Ship Channel. One site only monitors meteorology and any accidental releases. This site is the northeasternmost site and does not monitor for any organic compound. The study states that the prevailing wind direction is from the southeast (Ref. 21). Therefore, the monitoring sites are upwind from all but one of the cumene manufacturing and processing sites and are gathering data on cumene emissions from refineries and other unknown sources.

There is one manufacturing facility sited in the monitoring array. However, the facility appears to be at least 5 miles from the closest downwind monitoring site. Additionally, it is not clear from this study whether the detected environmental concentrations were detected at the closest downwind monitoring sites. The monitoring array is either upwind from all the other cumene manufacturing and processing sites or is over 30 miles away from these sites. At that distance, the facilities would have to release extremely large amounts of cumene per minute to reach detectable levels in the monitoring array. Therefore, it is unlikely that the data accurately assess the level of cumene present in close proximity to the facility.

The Cumene Panel submitted additional information on modelling performed at the Champlin Refining and Chemicals facility in Corpus Christi, Texas (Ref. 22). In this exercise, Champlin modelled point source air emissions from barges loading cumene. Annual emissions of cumene from these loading operations were estimated to be 23,000 pounds. However, there are shortcomings with the methodology employed in the study.

For modelling purposes, Champlin divided the annual point source release estimate by the total number of minutes in a year to derive the source term (mass release per minute). Champlin should have divided the annual point source release estimate by the total number of minutes per year in which barge loading occurred to derive a more realistic source term for modelling potential air concentrations. Based on a 1990 joint effort between EPA and the American Oil Company on the refining industry, EPA estimates that the capacity of an intercoastal barge or tanker ranges from 2.5 million to 70 million gallons. Based on an assumed 1 day fill rate and a 10 million gallon barge/tanker capacity, the entire capacity of production at the Champlin facility could be loaded in 7 days. If the cumene emissions were assumed to be released over a period of 7 days rather than 365 days, the source term (input) would be raised by a factor of 50. Additionally, Champlin used typical to better than average meteorological conditions of stability class C and a windspeed of 12 miles per hour in the modelling exercise. A more conservative, yet still realistic, set of meteorologic conditions would be a stability class of D and a windspeed of 5 miles per hour. Therefore, EPA believes the resulting ambient concentrations of cumene from the Champlin modelling exercise underestimate the ambient concentration of cumene resulting from releases at the Champlin facility.

Furthermore, EPA's review of the study indicates that the study does not shed any light on the number of people potentially exposed to cumene, rather it is only concerned with determining a level of cumene in the area of the Houston Ship Channel. Therefore, the study does not relate to whether EPA could make a substantial human exposure finding.

Another section of the remand evidence submitted by CMA consisted of modeling studies of ambient air concentrations of cumene that may result from emissions from several cumene manufacturing sites. Although all studies used the EPA Industrial Source Complex Long Term (ISCLT) air dispersion model, the level of detail concerning methods and assumptions used varied from study to study, thus inhibiting EPA's ability to adequately review the studies. Each of the studies is briefly discussed below.

Modelling of cumene emissions from two Georgia Gulf Corporation facilities, one in Plaquemine, Louisiana, and the other in Pasadena, Texas, were performed using "adjusted" EPCRA section 313 release data for reporting year 1987 (Ref. 23). The rationale to justify the procedure used to adjust the EPCRA section 313 release data and to justify the meteorological assumptions used for modeling air dispersion were not sufficiently detailed to enable an adequate EPA review of the study.

The study describing the modelling of cumene emissions from a Koch Refining Company facility (Ref. 24) provided sufficient details on methods and assumptions to allow for an adequate EPA review. This modelling study also purported using 1987 EPCRA section 313 release data. However, the annual releases used in the study, 1,971 pounds, show a large unexplained discrepancy with the 19,500 pounds of cumene emissions actually reported under EPCRA section 313.

Modelling studies for the Shell Oil Company Deer Park, Texas, facility (Ref. 25) and Texaco's El Dorado facility (Ref. 26) were also submitted. However, supporting data on the methods and assumptions used in the studies were not sufficiently detailed to enable an adequate EPA review of the studies.

The remand evidence was accompanied by an affidavit from Marvin B. Hertz, an industry consultant, supporting the use of ambient air monitoring data rather than the mass emission data from the EPCRA section 313 Toxic Release Inventory (TRI) (Ref. 27).

EPA recognizes that the use of ambient air monitoring data, when performed correctly, plays a role in any exposure assessment, and thus, in risk assessment. However, it is very difficult to perform any risk assessment when the hazards of the compound are either not known or not well characterized. For this reason, and the reasons articulated in Unit II.E. of this notice, EPA does not depend on human exposure at a particular "level" in determining "exposure" under TSCA section 4(a)(1)(B)(i).

Finally, the Cumene Panel stated that testing submitted pursuant to the final test rule confirms that cumene does not present a risk. Moreover, the Panel objected to EPA's reference to a TSCA section 8(e) submission, which indicated cataract formation in rats exposed to cumene vapors, as an example of the benefits of testing a chemical in the absence of hazard data. Since that section 8(e) submission, the

Panel has undertaken a follow-up subchronic study.

On June 17, 1992, utilizing data submitted in response to the cumene test rule, EPA held an RM1 disposition for cumene to determine whether to take risk management action on the chemical (Refs. 28 and 29). EPA determined that sufficient information for hazard assessment is available and supports a low concern. When the hazard information was considered in conjunction with available exposure information, EPA determined that cumene presents a relatively low risk to human health, and has discontinued review of this chemical at this time. Therefore, EPA does not believe any further testing of cumene is necessary at this time.

V. Public Record

A. Supporting Documentation

EPA has established a record for this policy under TSCA section 4, docket number OPPTS–47002K, which is available for inspection Monday through Friday, excluding legal holidays, in Rm. ET–G102, 401 M St., SW., Washington, DC., 20460 from 8 a.m. to 12 noon and from 1 p.m. to 4 p.m. This record includes basic information considered by EPA in developing this policy. This record includes the following information:

(1) Interagency memoranda, comments, and proposals.

(2) Reports-published and unpublished data.

(3) Chemical Manufacturers Association v. EPA, 899 F.2d 344 (5th Cir. 1990).

B. References

(1) The Chemical Manufacturers Association. Comments on EPA's TSCA section 4(a)(1)(B) Proposed Statement of Policy submitted to the TSCA Public Docket Office, USEPA (September 17, 1991).

(2) Epoxy Resin Systems Task Group of The Society of the Plastics Industry, Inc. Comments on EPA's TSCA section 4(a)(1)(B) Proposed Statement of Policy submitted to the TSCA Public Docket Office, USEPA (September 17, 1991).

(3) Monsanto Company. Comments on EPA's TSCA section 4(a)(1)(B) Proposed Statement of Policy submitted to the TSCA Public Docket Office, USEPA (September 12, 1991).

(4) Ecological and Toxicological Association of the Dyestuffs Manufacturing Industry. Comments on EPA's section 4(a)(1)(B) Proposed Statement of Policy submitted to the TSCA Public Docket Office, USEPA (September 17, 1991).

(5) Callery Chemical Company. Comments on EPA's section 4(a)(1)(B) Proposed Statement of Policy submitted to the TSCA Public Docket Office, USEPA (September 18, 1991).

(6) Halogenated Solvents Industry Alliance. Comments on EPA's section 4(a)(1)(B) Proposed Statement of Policy submitted to the TSCA Public Docket Office, USEPA (September 19, 1991).

(7) GAF Chemicals Corporation, BASF Corporation, and ARCO Chemical Company. Comments on EPA's section 4 (a)(1)(B) Proposed Statement of Policy submitted to TSCA Public Information Office, USEPA (September 17, 1991)

(8) U.S. Department of Labor, Occupational Safety and Health Administration. Comments on EPA's section 4(a)(1)(B) Proposed Statement of Policy submitted to TSCA Public Docket Office, USEPA (October 7, 1991).

(9) U.S. Department of Health and Human Services, National Institute for Occupational Safety and Health. Comments on EPA's section 4(a)(1)(B) Proposed Statement of Policy submitted to TSCA Public Docket Office, USEPA (September 17, 1991).

(10) CMA's Acetone and Ketones Panel. Comments on EPA's section 4(a)(1)(B) Proposed Statement of Policy submitted to TSCA Public Information Office, USEPA (September 17, 1991).

(11) CMA's Oxo Process Panel. Comments on EPA's section 4(a)(1)(B) Proposed Statement of Policy submitted to TSCA Public Information Office, USEPA (September 17, 1991).

(12) CMA's Cumene Panel. Comments on EPA's section 4(a)(1)(B) Proposed Statement of Policy submitted to TSCA Public Information Office, USEPA (September 17, 1991).

(13) CMA's Cyclohexane Panel. Comments on EPA's section 4(a)(1)(B) Proposed Statement of Policy submitted to TSCA Public Information Office, USEPA (September 17, 1991).

(14) CMA's Hexamethylene Diisocyanate Panel. Comments on EPA's section 4(a)(1)(B) Proposed Statement of Policy submitted to TSCA Public Information Office, USEPA (September 12, 1991).

(15) Diethyl Ether Manufacturers Task Group. Comments on EPA's section 4(a)(1)(B) Proposed Statement of Policy submitted to TSCA Public Information Office, USEPA (September 15, 1991).

(16) USEPA. Implementation Proposal; "New Chemicals Exposure-Based Finding," letter from Charles L. Elkins to Geraldine V. Cox (Chemical Manufacturers Association). Office of Toxic Substances, USEPA (September 22, 1988).

(17) Organization for Economic Cooperation and Development. "OECD's Work on Investigation of High Production Volume Chemicals." Document 3, May 1991.

(18) U.S. Department of Health and Human Services, National Institute for Occupational Safety and Health. National Occupational Exposure Study (NOES,1988).

(19) Radian Corp. A Method for Assessing Community Exposure to Selected Volatile Indicator Compounds (July 20, 1988). (CMA exhibits for remand evidence).

(20) USEPA. Review of Evidence Submitted by CMA on Remand of Cumene Test Rule. Washington, DC: Office of Pollution Prevention and Toxics, USEPA (April, 1992).

(21) Radian Corp. Volatile Indicator Compound Measurement Results from the Houston Regional Monitoring Network, Phase IV (July 20, 1988). (CMA exhibits for remand evidence).

(22) Champlin Refining Company. Air Modelling of Cumene Releases at Champlin Refining Company (October 14, 1988). (CMA exhibits for remand evidence).

(23) Georgia Gulf Corporation. ISC and ISCLT Air Modelling Results from Georgia Gulf Corporation Facilities (December 16, 1988) (CMA exhibits for remand evidence).

(24) Koch Refining Company. Air Modelling Results from Koch Refining Company Facility (October 20, 1988) (CMA exhibits for remand evidence).

(25) Shell Oil Company. Air Modelling Results from Shell Deer Park Facility (Undated) (CMA exhibits for remand evidence).

(26) Star Research. Air Modelling Results from Texaco's El Dorado Facility (September 30, 1988) (CMA exhibits for remand evidence).

(27) Hertz, Marvin A. Affidavit on Use of Monitoring Data versus Mass Emission Data (CMA exhibits for remand evidence).

(28) USEPA. Regulatory Management-1 (RM1) Summary for Cumene. Washington, DC: Office of Pollution Prevention and Toxics, USEPA (January 10, 1991).

(29) USEPA. Regulatory Management-1 (RM1) Summary for Cumene. Washington, DC: Office of Pollution Prevention and Toxics, USEPA (June 17, 1992).

Dated: May 5, 1993.

Victor J. Kimm,

Acting Assistant Administrator for Prevention, Pesticides and Toxic Substances.

[FR Doc. 93–11496 Filed 5–13–93; 8:45 am]

BILLING CODE 6560–50–F